

## Appendix 9

### Technical Documents for the Application of Drug Review and Registration of API

Documents should be submitted (Note3)	For Common Pharmaceutical Preparation	API for Exportation
Checklist of the documents for API applying for Exportation	×	○
Information of the organization and personnel of the manufacturing site as in the CTD document	△	× (Note1)
Background information of final products and the basis of manufacturing methods	△	×(Note1)
Manufacturing and control data	△	×(Note1)
Specifications, testing equipment, testing methods and testing records	○	△(Note2)
Stability study data	△	×(Note1)

Note:

- : submission required; ×: not required ; △: on a case-by-case basis
- 1 Do not need to be submitted with the application, but these documents should be retained for future inspection.
  - 2 Except for specifications, testing methods and certificate of analysis other relevant documents are not required for the application, but are needed to be retained for future inspection.
  - 3 Application dossiers shall be submitted according to the Common Technical Document (CTD) format.